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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,894	12/15/1999	MARC PIECHACZYK	19141-007	5731

7590 08/24/2006

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EXAMINER	
WOITACH, JOSEPH T	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/341,894	PIECHACZYK ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52,53,55,57,60 and 61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52,53,55,57,60 and 61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 12, 2006 has been entered.

DETAILED ACTION

This application is a 371 national stage filing of PCT/FR98/00081, filed January 16, 1998 which claims benefit to foreign application FR 97/00540, filed January 20, 1997 in France.

Applicants' amendment filed June 12, 2006 has been received and entered. Claims 1-51, 54, 56, 58 and 59 have been canceled. Claim 52 has been amended. Claims 60-61 have been added. Claims 52, 53, 55, 57, 60 and 61 are pending and currently under examination.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claims Objection

Claim 52 is objected to because of the following informalities: the claim recites "and able to a long life" and "up to until lifetime to the patient" in the final lines of the claim, which is not correct English.

Claim 57 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In this case, claim 57 indicates that the antibody is detected in the blood of a subject, however this appears to be a requirement and inherent property of independent claim 52 .

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52 and 60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". There are two separate issues: first, the recitation of "without triggering an anti-idiotype respons

directed against said antibody in said mammal"; and second, the embodiments of newly added claim 60.

With respect to claim 52, Applicants do not point to support for the amendment, but upon review support for the term "anti-idiotype" can be found in the specification at paragraphs 96 and 97 of the working examples at the end of the specification. This provides at best support for the amendment with all the specifics set forth in this example. More specifically, the disclosure provides the general guidance for producing an antibody in a subject, however fails to address any issue regarding and immune response(s) and antibody production in said subject to the production of a foreign antigen, in this case a recombinant antibody. In view of the art of record, there is no inherent property of the general delivery method that would prevent the immune system of a mammal to react to a new foreign antigen, and more specifically one that would prevent antibodies displaying an anti-idiotype property.

Similar to above, the embodiments of claim 60 finds literal support only in a working example in paragraphs 85 and 92 as they are directed to Tg10 antibody. There is no general teaching nor guidance in the specification for what or how thermodynamic and kinetic properties are assayed. Further, the working example only provides for the measurement of Tg10 by surface plasma resonance to be identical, not any thermodynamic or kinetic property.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 52 and 60 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has

not been described. In both cases, the present specification fails to provide any guidance for overcoming the natural response of a mammal to a foreign antigen nor for providing a recombinant protein in an artificial system that maintains all the thermodynamic and kinetic properties of a antibody encompassed and inherently present when first produced in another system. For example, US Patent 6,426,088 provides examples where certain levels of Tg10 in mice would produce an anti-idiotype response in 6 of 13 mice tested (column 10). Further, with respect to one possible thermodynamic or kinetic property to be tested, expression levels of Tg10 were reduced over time (column 9) clearly demonstrating that even the present specification for single example provided, production of Tg10, fails to meet the limitation of the claims.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52, 53, 55, 57, 60 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically;.

Claim 52 has been amended to recite that the method is practiced "without triggering an anti-idiotype response directed against said antibody in said mammal" however there are no method steps to how this is accomplished. The claimed method appears to be incomplete lacking essential method steps to how one would prevent triggering a response in a mammal to a foreign antigen, in this case an anti-idiotype response to a foreign antibody in a mammal.

Claim 57 is unclear and indefinite in the recitation of "detectable" because it is relative to how one would detect. Initially, it is noted that the presence of an antibody in the blood produced in the method of claim 52 appears to be a requirement and inherent, and it is unclear in part how claim 57 further limits claim 52. With respect to detectable, this term is indefinite because how the antibody is "detected" would affect the metes and bounds of the claim, so is subject and relative to the method used.

Claim 60 is vague and indefinite because how and what properties are assayed are not clearly set forth. Further, the claim appears to be incomplete and lacks sufficient antecedent basis for the limitation relative to claim 52 because it fails to establish that the sequence used in the generating a genetically modified cell had any particular property associated with it that could or would be measured. Alternatively, it fails to limit claim 52 because this would be an inherent property of the antibody produced.

Claim 61 is vague and incomplete in the recitation of "therapeutically effective" because what therapy is encompassed or to be affected by the general method of delivery set forth in claim 52 is not clearly set forth. If it is a "therapeutic antibody" being produced (as generally taught in the specification-paragraph 16), there is insufficient antecedent basis for this in claim 52, even if so amended the claim appears not to further limit claim 52 in that it would be an inherent property of practicing the method.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 52, 53, 55 and 57 rejected under 35 U.S.C. 102(b) as being anticipated by Wright *et al.* (1992) is withdrawn.

Claims 52, 53, 55 and 57 rejected under 35 U.S.C. 102(b) as being anticipated by Stevenson *et al.* is withdrawn.

Claims 52, 53, 55 and 57 rejected under 35 U.S.C. 102(b) as being anticipated by Chen *et al.* (1994) or Chen *et al.* (1996)is withdrawn.

In view of the amendments to the claims the claimed invention is differentiated from that of the cited references and therefore, the rejections are withdrawn. In particular it is noted that the methods of producing an antibody in a mammal demonstrated by Stevenson *et al.* and Chen

et al. while meeting the structural limitations of the instant claims, were practiced to induce an immune response. Similarly, Wright *et al.* provide a wide arrange of vectors and delivery systems including nonlymphoid cell expression (page 130, section 6) for genetically engineered antibody production, and provide guidance for their use in clinically relevant applications (page 141, section V) it fails to specifically teach or discuss methods of implantation of a cell for the production of said antibody.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 6,426,088 (Piechaczyk *et al.*) provides methods for encapsulating antibody producing cells, however fails to teach the use of non-plamocytes or more generally the production of recombinant proteins/antibodies.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach